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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/506,579

04/13/2005

Jorg Sturzebecher

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21559

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12/16/2009

CLARK & ELBING LLP
101 FEDERAL STREET
BOSTON, MA 02110

EXAMINER

ZUCKER, PAUL A

ART UNIT

PAPER NUMBER

1621

NOTIFICATION DATE

DELIVERY MODE

12/16/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentadministrator@clarkelbing.com

Office Action Summary	Application No. 10/506,579	Applicant(s) STURZEBECKER ET AL.	
	Examiner Paul A. Zucker	Art Unit 1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-40 is/are pending in the application.
- 4a) Of the above claim(s) 22-27,30-33 and 39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21,28,29,34-38 and 40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 21-40 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 22 September 2009 has been entered.

Current Status

2. This action is responsive to Applicants' amendment of 22 September 2009.
3. Receipt and entry of Applicants' amendment is acknowledged.
4. Applicant's cancellation of claims 1-20 is acknowledged.
5. Claims 21-40 are pending.
6. The rejection under 35 USC § 102, set forth in paragraph 6 of the previous Office Action mailed 30 January 2009 is withdrawn in view of the fact that R₄ is required to be a group other than hydrogen in the presently claimed compounds. A new rejection under 35 USC § 102 is set forth below.

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New Rejections

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Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 21, 28, 29, 34-38 and 40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 21 recites the limitation "characterized in that one or more charged radicals, ~~preferably~~ derived from-COOH, -CH(COOH)₂, -SO₂H, NH₂, an amidino, hydroxyamidino, amidrazono, or guanidino group, is/are present in the radicals R₁, R₂, R₃ or R₅" in lines 59-61. It is unclear from this recitation which groups are encompassed in the claim for several reasons:
- a. It is unclear what the structures of the encompassed groups are, since an infinite variety of structures are derivable from the listed functional groups due to the ability of the ordinary artisan to convert, through a variety of synthetic transformations, any arbitrary functional group into any other functional group.
 - b. It is unclear whether a particular functional group meets the "charged" limitation if it can be charged under some conditions and not others (e.g. guanidino or hydroxyl groups) or the group must retain its charge regardless of the chemical context in which it finds itself (e.g. a quaternary ammonium group).
 - c. If Applicants intend that a particular functional meets the "charged" limitation if it can be charged under some conditions and not others, no conditions are specified and it is therefore impossible to determine whether any particular functional group meets this limitation.

For these reasons claim 21 and its dependents are rendered indefinite.

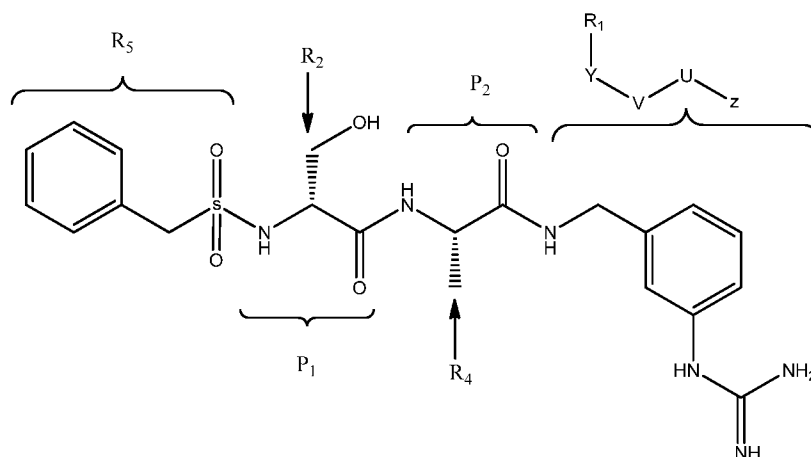
Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 21 and 34-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Levy et al (WO 02/14349-A2 02-2002). Levy discloses (Page 96, lines 10-26) the compound benzensulfonyl-D Ser-L-Ala-guanidinobenzylamide in trifluoroacetic acid solution. This corresponds to a compound of the invention in which the groups have the correspondences shown:



Under these conditions the hydroxyl group in R_2 will be protonated to a large extent and thus positively charged. Levy discloses (Page 70, line 16-page 71, line 11) a similar compound in which the R_5 group is an alkylsulfonyl group. Levy discloses

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(Page 63, lines 12-21) oral administration of pharmaceutical compositions of the compound. This route of administration subjects the compounds to the highly acidic environment of the stomach.

Examiner's Response to Applicants' Remarks With Regard to the Prior Rejection

9. Applicants' sole argument is that the compound benzensulfonyl-D SerGly-amidinobenzylamide does not have the required charged group in R₁, R₂, R₃, or R₅. The Examiner, however, notes that the hydroxymethyl group (derivable from a COOH group) on the serine residue can be protonated and thus assume a positive charge. This is especially true in the acidic environment of the stomach or in the presence of trifluoroacetic acid.

Applicant's arguments filed 30 January 2009 have been fully considered but they are not persuasive for the reasons set forth above.

Conclusion

10. Claims 21-40 are pending. Claims 21, 28, 29, 34-38 and 40 are rejected. Claims 22-27, 30-33 and 39 are held withdrawn from consideration as being drawn to a non-elected invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul A. Zucker whose telephone number is 571-272-0650. The examiner can normally be reached on Monday-Friday 5:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel Sullivan can be reached on 571-272-0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Paul A. Zucker/
Primary Examiner, Art Unit 1621